

Please insert new claims 26-61 as follows:

B2 --26. Micro cellular polyhipe polymer scaffold suitable for growth of living matter for biomedical applications, comprising a homogeneous cross linked open cellular material defined by a bulk polymer matrix having a surface and an interface with an internal phase, and having porosity greater than 75% comprising emulsion derived pores of diameter in the range of 0.1 to 10,000 micron and emulsion derived pore interconnects of diameter in the range of up to 100 micron, wherein the scaffold comprises a plurality of discrete zones with location selected from:

at the polymer surface;

within its bulk matrix;

at the interface between polymer and internal phase; and

between adjacent but distinct pores or interconnects, characterized by form and dimension of pore and interconnect type within each zone, and location of zones wherein adjacent zones are distinguished by boundaries, whereby zones are suitable for regulating positioning and morphology of living matter, wherein the scaffold comprises controlled pore sizes selected from the range up to 0.5  $\mu\text{m}$ , up to 300  $\mu\text{m}$ , up to 10,000  $\mu\text{m}$ , and up to nm size and comprises pore interconnects selected from the range up to 100 micron, and approaching 500 micron, characterized in that the scaffold comprises pore and interconnect sizes in different ranges in two or more distinct zones.

27. Microcellular polyhipe polymer scaffold as claimed in Claim 26 wherein discrete zones are interpenetrating.

28. Microcellular polyhipe polymer scaffold as claimed in Claim 27 obtainable by polymerizing a high internal phase emulsion of an immiscible dispersed phase in a continuous phase, wherein the dispersed phase is void or contains dissolved or dispersed materials, and (co)monomers, oligomers and/or pre-polymers are present in the continuous phase, by means of introducing the dispersed phase by controlled dosing into the continuous phase with controlled mixing at controlled emulsification temperature and rate to achieve an emulsion of controlled pore size, and subsequently homogenizing for controlled period under controlled deformation and polymerising under controlled temperature and pressure, characterized in that controlled pore size approaching 0.1  $\mu\text{m}$  up to 0.5  $\mu\text{m}$  is obtained using very high deformation rate flows in which the flow is predominantly extensional and low emulsification temperature, pore size up to 300  $\mu\text{m}$  is obtained using rate just above the critical deformation rate at which phase inversion takes place and high emulsification temperature, very large pore size up to 10,000  $\mu\text{m}$  is obtained through the method of controlled pore coalescence during polymerization, and nano-pore size up to nm is obtained through solvent extraction after polymerization; and in that microcapillaries of diameter in the range 10 – 1000  $\mu\text{m}$  is obtained by polymerising about a 3D network of fibers and in that differing pore and interconnect sizes are obtained by co-extrusion of polyhipe emulsions.

29. Microcellular polyhipe polymer scaffold as claimed in Claim 28 wherein microcapillary networks are present within the emulsion derived pores.

30. Micro cellular polyhipe polymer scaffold as claimed in Claim 29 comprising more than one type of microcapillary.

31. Micro cellular polyhipe polymer scaffold as claimed in Claim 30 wherein each microcapillary type is distinguished by diameter, surface modification, interface porosity or pore size or chemical structure.

32. Micro cellular polyhipe polymer scaffold as claimed in Claim 31 wherein emulsion derived pores comprise nano-porous walls which are void, increasing the size of interconnects or which contain filler polymers for extra strength.

33. Microcellular polyhipe polymer scaffold as claimed in Claim 32 suitable for growth of living matter selected from cells, micro-organisms such as bacteria and virus and mixtures thereof.

34. Microcellular polyhipe polymer scaffold as claimed in Claim 33 comprising micro channels formed of pores with interconnects suitable for providing communication and penetration of living matter for anisotropic (directional) growth thereof.

35. Microcellular polyhipe polymer scaffold as claimed in Claim 34 wherein the walls of the micro-channels are (bio)degradable suitable for fusion of living matter in the (bio)degraded scaffold.

36. Microcellular polyhipe polymer scaffold as claimed in Claim 35 comprising in individual zones, pore and interconnect sizes in different ranges, suitable for co-culturing two or more types of living matter.

37. Microcellular polyhipe polymer scaffold as claimed in Claim 36 wherein ratio of interconnect to pore diameter is in the range  $0 < d/D < 0.5$  when the pore diameter is approximately less than 200 micron.

38. Microcellular polyhipe polymer scaffold as claimed in Claim 37 comprising extensive networks of elongate micro capillaries obtainable by moulding about fibrous inserts of diameter in the range from 10 micron up to 1000 micron, throughout the scaffold or zones thereof, separated by the microcellular polymer wherein microcapillaries are suitable for blood or nutrient supply channels, expression channels for living matter and seeding of living matter.

39. Microcellular polyhipe polymer scaffold as claimed in Claim 38 wherein the interface between a microcapillary wall and the bulk polymer provides a thin surface layer of the order of 0.5-5 micron, forming a zone particularly suited for directional (anisotropic) growth of living matter.

40. Microcellular polyhipe polymer scaffold as claimed in Claim 39 wherein the interface has smaller pore size than the bulk polymer wherein the zone is suitable for growth of cells forming a

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lining, for example cells lining the blood vessels or for growing endothelial cells on the interface surface.

41. Microcellular polyhipe polymer scaffold as claimed in Claim 40 comprising a module of shell and tube type or cubic/polyhedric type with respect to direction and/or configuration of channels and/or microcapillaries.

42. Microcellular polyhipe polymer scaffold as claimed in Claim 41 comprising a surface coating, using coating materials introduced in situ during polymerization or post polymerization

43. Microcellular polyhipe polymer scaffold as claimed in Claim 42 wherein polymer is selected from proteins and cellulose, polyacrylamide, polyvinyl in rigid or flexible form, poly(lactic acid), poly(glycolic acid), polycaprolactone, poly(lactide/glycolide) and polyacrylimide.

44. Microcellular polyhipe polymer scaffold as claimed in Claim 43 wherein polymer comprises resiliently deformable or elastic material or is rendered resiliently deformable or elastic and is suitable for repeated stress and relaxation by means of oscillatory straining of the scaffold during cell growth facilitating rate of cell growth.

45. Microcellular polyhipe polymer scaffold as claimed in Claim 44 wherein polyhipe scaffold is electrically conductive or is rendered electrically conductive whereby it is suitable for conducting an electric current during cell growth, facilitating distinguishing certain cell types and promoting growth and fusion of particular cell types

46. A process for the preparation of a microcellular polyhipe polymer scaffold as hereinbefore defined comprising in a first stage the formation of a high internal phase emulsion (HIPE) of an immiscible dispersed phase in a continuous phase, wherein the dispersed phase is void or contains dissolved or dispersed materials, and (co)monomers, oligomers and/or pre-polymers are present in the continuous phase, by means of introducing the dispersed phase by controlled dosing into the continuous phase with controlled mixing at controlled temperature and rate to achieve an emulsion of controlled pore size, and subsequently homogenising for controlled period under controlled deformation and polymerising under controlled temperature and pressure wherein controlled pore size of emulsions up to 0.5  $\mu\text{m}$  are obtained using very high deformation rate flows in which the flow is substantially extensional and high emulsification temperature, pore size up to 300  $\mu\text{m}$  are obtained using rate just above the critical deformation rate at which phase inversion takes place, very large pore size up to 10,000  $\mu\text{m}$  are obtained through the method of controlled pore coalescence during polymerisation, and nano-pore size up to nm are obtained through solvent extraction after polymerization and microcapillaries are obtained by polymerising about a 3D network of fibers.

47. Process as claimed in Claim 46 wherein very large pore size up to 10,000  $\mu\text{m}$  are obtained by adding water soluble polymer to the aqueous phase or filler solutes to the oil phase at elevated concentrations with controlled pore coalescence during polymerization.

48. Process as claimed in Claim 47 wherein nano-pore size up to nm are obtained using an oil phase filler selected from high boiling point hydrocarbon, another monomer or macromonomer, reactive or inert polymer and/or solid particles optionally with solvent extraction after polymerization.

49. Process as claimed in Claim 48 comprising co-extrusion of polyhipe emulsions of differing pore and interconnect sizes eg concentrically or side-by-side.

50. Process as claimed in Claim 49 using multiple-feed points with a prolonged dosing to create a large pore emulsion.

51. Process as claimed in Claim 50 wherein emulsification temperature is greater than 60C.

52. Process as claimed in Claim 51 wherein homogenisation temperature is in the range 60 - 150C.

53. Process as claimed in Claim 52 carried out with use of additional oil phase initiator.

54. Process as claimed in Claim 53 carried out with use of additional oil phase filler.

55. Process as claimed in Claim 54 wherein the emulsion comprises aqueous and non-aqueous phases.

56. A biologically active system comprising a polyhipe scaffold as defined in Claim 26 and living matter providing normal cell functioning associated with a natural biologically active system present in the human or animal body, wherein living matter is selected from microorganisms or multiple cells selected from human, animal and plant cells, preferably selected from isotropic tissue and bone cells present in cartilage, cornea, marrow and the like, anisotropic cells such as nerve, muscle, blood vessel cells, of cell type selected from fibroblasts, chondrocytes, osteoblasts, bone marrow cells, hepatocytes, cardiomyocytes, neurons, myoblasts, macrophages and microvascular endothelium cells.

57. Method for growth of multiple cells in a polyhipe scaffold as hereinbefore defined in Claim 26 comprising providing cells on or in the scaffold in a controlled environment and providing a suitable nutrient adapted for growth and providing conditions for growth promotion and positional control.



58. Use of a biologically active system as defined in Claim 56 as an implant or in association in vivo in or with the human or animal body or as a module for in vitro studies mimicking a part of the human or animal body or for use in a growth environment, for example for the growth of organ cells in the cell side of the module in order to stimulate organs.

59. An organ support module comprising a cubic or polyhedric module of closely interwoven but not interconnecting channels immersed in a polyhipe scaffold as defined in Claim 26 suited for growth of specific organ cells in the polyhipe and/or the channels, wherein cells are optionally in contact with a specific microchannel and all cells are capable of intercell communication.

60. A method for manufacturing an organ support module as defined in Claim 59 comprising providing a polyhipe emulsion, providing a mould including inserts such as rods or fine fibres, pumping polyhipe emulsion and optional filler into the mould about the inserts and polymerising, with subsequent removal of inserts and optional filler to provide pores and interconnects, microcapillaries and nano-pores in desired configuration.

61. The use of a polyhipe scaffold, a biologically active system, or organ support module as defined in Claim 26, for the manufacture of contact lenses, dental fillings, cochlea implants, vascular supports including heart valves and cardiac pace makers and drug delivery skin patches.